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18N1/0422

MOSHER, M EXAMINER	
ART UNIT	PAPER NUMBER
1813	26

DATE MAILED: 04/22/96

Please find below a communication from the EXAMINER in charge of this application.

Commissioner of Patents

All claims are allowable. However, due to a potential interference, ex parte prosecution is SUSPENDED FOR A PERIOD OF SIX MONTHS FROM THE DATE OF THIS LETTER.

Upon expiration of the period of suspension, applicant should make an inquiry as to the status of the application.

See the attached statement regarding reasons for indicating allowable claims.

April 19, 1996

*Mary Mosher*

MARY E. MOSHER  
PRIMARY EXAMINER  
GROUP 1800

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The following is an Examiner's Statement of reasons for indication of allowable claims:

The terminal disclaimer filed on November 22, 1995, disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of patent 4,603,112 has been reviewed and is accepted. The terminal disclaimer has been recorded.

On reconsideration, the rejection of claims 33, 34, 41, 42, 43, 50, and 51 under 35 U.S.C. § 102 as anticipated by Mackett et al (AX) is withdrawn, and the rejection of claims 38, 47, and 49 under 35 U.S.C. § 103 as obvious over Mackett et al (AX) is withdrawn. Mackett et al is not available as prior art for the parent applications filed on or before December 8, 1982.

On reconsideration, it would have been apparent to the skilled artisan as of December 24, 1981 that expression of the HSV TK gene in the HindIII F fragment was under vaccinia control. The reason it would have been apparent is that three independent recombinants, in the orientation corresponding to "clockwise" in Figure 3C, all expressed the HSV TK gene; while three independent recombinants, all in the "counterclockwise" orientation, all failed to express the HSV TK gene. It would have been apparent that the expression was not dependent upon the presence of a tandem insert in the "counterclockwise" constructs, because at least one of the constructs deleted one of the tandem copies, see

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column 13 lines 12-15. While one skilled in the art could readily believe that a deletion could inactivate an otherwise expressible gene, one would not have readily believed that a deletion would have specifically activated expression, in three independent constructs. Since expression in one orientation but not the other was known at the time to be characteristic of control by a cis-acting control element, it would have been apparent that the cis-acting element was a part of vaccinia. Therefore the earliest filed parent application 06/334,456 (patent 4,769,330) discloses one species which is within the scope of the broadly claimed subject matter.

The disclosure of December 8, 1982, application 06/446,824 (patent 4,603,112) provides working examples of expression under vaccinia control in two different parts of the vaccinia genome. There also is literal support for a promoter within HindIII F, see figure 9C. The prevailing contemporary thinking in the art was that vaccinia produced a large number of transcripts; therefore one skilled in the art would have expected the vaccinia genome to contain a large number of functional promoters, and little guidance would have been needed to obtain additional functional combinations of promoters and foreign genes. The representative examples are therefore seen as providing adequate support at least on December 8, 1982 for a generic claim of "expression under vaccinia control".

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. Mosher, Ph. D., whose telephone number is (703) 308-2926. The examiner can normally be reached on Monday-Thursday from 6:30 AM-4:00 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christine Nucker, can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

April 19, 1996

  
MARY E. MOSHER  
PRIMARY EXAMINER  
GROUP 1800